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From a Disposable Ureteroscope to an Active Lightweight Fetoscope - Characterization and Usability Evaluation

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***Abstract*—The twin-to-twin transfusion syndrome (TTTS) is a severe fetal anomaly appearing in up to 15% of identical twin pregnancies. This anomaly occurs when twins share blood vessels from a common placenta. The complication leads to an unbalanced blood transfusion between both fetuses. A current surgical treatment consists in coagulating the shared vessels using a fetoscope with an embedded laser. Such treatment is very delicate and constraining due to limited vision and size of the insertion area. The rigidity and lack of controllability of the current used instruments add an additional difficulty and limit the choice in insertion site. This work proposes an improved flexible fetoscope, offering an enhanced laser controllability and higher versatility regarding the location of the insertion site. A better approach angle can therefore be realized. Also, tissue damage may be further reduced. This single-handed controllable active fetoscope is obtained after adaptation of a LithoVue (Boston Scientific, Natick, USA), a commercially available passive flexible ureteroscope. The LithoVue is fitted with a unique lightweight add-on actuation module foreseen of an artificial muscle and a dedicated control system. Experiments in a mixed reality trainer suggested that the proposed fetoscope is compact, ergonomic and intuitive in use, allowing an adequate control of the flexible end.**

***Index Terms*—Medical Robots and Systems, Flexible Robots, Mechanism Design.**

I. INTRODUCTION

THE twin-to-twin transfusion syndrome (TTTS) is a serious fetal complication occurring in monozygotic twins sharing a single placenta, but separate amniotic sacs. This fetal anomaly, which occurs in 10 to 15% of monochrionic twin pregnancies [1], results from a disproportional blood transfusion from one twin to the other. The *donor* fetus transfers blood to the *recipient* fetus, impeding the *donor* fetus's proper development. If left untreated, severe TTTS can lead to a near-100% mortality rate. However, endoscopic laser ablation (ELA) of placental vessels allows a trend reversal and can guarantee the survival of at least one twin in 75 to 80% of the cases [1]. This minimally invasive surgery (MIS) consists in inserting a straight fetoscope equipped with a therapeutic laser fiber in the cannula through the maternal abdominal and uterine wall. As such, it provides access into the amniotic sac of the *recipient* twin. The fetoscope is used to visualize the blood vessels on the placenta surface. By using the embedded laser, the surgeon is able of coagulating the placental vessels responsible for the blood transfusion between twins, as shown in Fig. 1 [2].

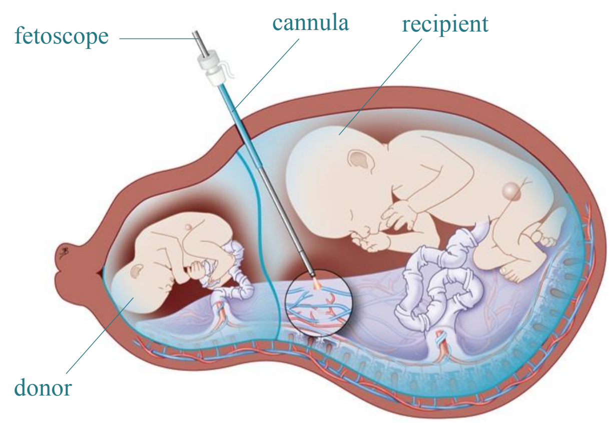

Fig. 1. Monozygotic twins suffering from TTTS in the maternal womb. A cannula is inserted through the maternal abdominal wall allowing the insertion of a fetoscope. The embedded scope and laser of the fetoscope allow the surgeon to coagulate the vessels responsible for the transfusion (Courtesy of UZ Leuven).

Compared to other forms of surgery, the current surgical treatment of TTTS presents important challenges: 1) the vision is blurred due to the turbid nature of the amniotic fluid [3]; 2) the diameter of the incision at the single insertion site must be sufficiently small to avoid iatrogenic preterm premature rupture of membranes (IPPROM) [4]; 3) the instrument workspace is limited due to the considerable thickness of the abdominal wall. Any stress applied on the

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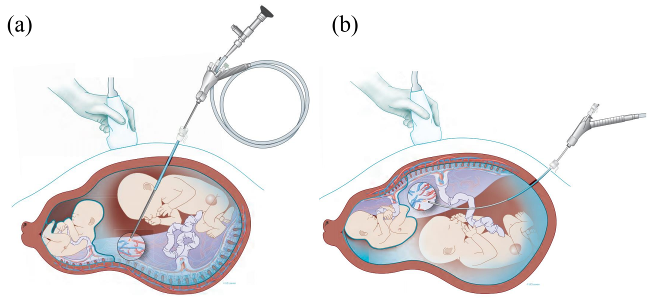


Fig. 2. Possible positions of the placenta in the uterus and corresponding used instrument. a. use of a straight fetoscope for *posterior* positioning of the placenta. b. use of a curved fetoscope for *anterior* positioning of the placenta (Courtesy of UZ Leuven).

uterus and fetal membranes may cause premature delivery [5].

The complexity of the ELA is partially caused by the rigid nature of current instruments (rigid and semi-rigid scopes) and their poor controllability. The low dexterity of these instruments severely restricts the number of potential insertion sites. When operating *anterior* located placentas (Fig. 2b), surgeons are forced to approach the targets under obtuse angles, worsening the visualization and limiting the ablation precision. As a consequence, practitioners tend to apply large forces at the incision site that may lead to tissue damage or cause IPPROM [5].

As an attempt to solve the above-mentioned issues and limitations, several fetoscopes with embedded laser have been reported in the literature. For example, Yamanaka *et al.* [6] designed a rigid endoscope which allows steering of a laser beam by control of mirror orientation. However, this endoscope presents a limited steering angle and a large external diameter, making it impractical in case of *anterior* location of the placenta. This mirror approach does not provide a steering of the camera, leading to a fixed vision range. To overcome this limitation and offer larger laser steering angles while keeping the vision range on the laser target, some steerable flexible manipulators have been introduced [3] [7] [8] [9]. Although their respective workspaces are interesting for TTTS treatment, these instruments only foresee the insertion of a single tool (laser, camera or forceps). An extra instrument is therefore needed for illumination and/or visualization purposes, meaning that extra incisions need to be made. These extra cuts may result in additional complications. Moreover, an additional surgeon is needed for the manipulation of this extra tool. This paper proposes a steerable flexible instrument with large laser and vision steering angle range. This single instrument contains all the necessary tools to perform a TTTS procedure, namely a camera, an illumination fiber and a working channel, allowing the insertion of a coagulation laser while keeping similar external diameter dimensions than proposed fetoscopes in the literature. Moreover, this novel fetoscope has been designed to be comfortably single-handed-controlled, which limits the number of surgeons needed for the surgical procedure.

The layout of this paper is as follows: first, the detailed ELA of placental vessels is described in section II. Section III addresses the design instrument specifications. An adjustment of an ureteroscope is proposed in section IV followed by an identification and characterization of the proposed solution. In section V, a protocol for user experiments is proposed and results are presented. Finally, section VI concludes the proposed work.

II. PROCEDURE SPECIFICATIONS

An ELA procedure of placental vessels is carried out as follows: initially, a detailed ultrasound inspection of the womb is performed in order to locate the placenta, the amniotic membrane separating the twins, the placental insertion of the umbilical cords and any extra fetal defects if such are present [10]. The most adequate entry site on the maternal abdomen is then chosen for cannula insertion, while avoiding any placental or fetus injuries. The cannula is preferably placed perpendicularly to the shared placenta, in such a way that the fetoscope with embedded laser can properly ablate the vessels. In this way, a good view of the targeted area is available, and the laser energy can be delivered in a focused region and not spread out due to the inclination. Usually, a neodymium-yttrium aluminum garnet (Nd-YAG) or a diode laser is used to ablate the vascular anastomoses [11].

In the womb, the placenta can be situated either on the *posterior* or on the *anterior* side. In the case of a *posterior* position, a straight rigid fetoscope is used (Fig. 2a) because a straight access path from the insertion site to the placenta is available. However, an *anterior* position of the placenta constraints the surgeon to resort to a semi-rigid curved fetoscope (Fig. 2b). In both cases, when inclining the instrument to ablate targeted vessels, stresses are applied on the uterine wall and on the amniotic sac during the ablation.

The use of a flexible instrument could reduce these stresses, but also provide a single instrument intended to be used in both cases of *posterior* and *anterior* positions of the placenta. The external diameter of the currently used fetoscopes varies between 2.3 and 4.0 mm. A new flexible instrument should adhere to these outer dimensions. Petersen et al. linked the increase diameter of the instrument with a higher likelihood of preterm birth [12]. Following this reasoning, the instrument diameter therefore needs to be as small as possible. Yet it must allow insertion of a camera, an illumination system and a therapeutic laser. The maximum bending angle of the flexible device has been fixed to 90°, allowing large freedom of movement for ablation of the selected vessels irrespective of the position of the placenta (Fig. 2) without exerting too much pressure on the uterus and fetal membranes. The bending should also be limited to one direction, as requested by fetal surgeons, in the hope that it would reduce the learning curve somewhat. The total instrument length ought to be somewhere between 188 mm to 306 mm, which is similar to fetoscopes available on the market nowadays [13].

TABLE I
SPECIFICATIONS FOR AN ACTIVE FETOSCOPE - PART 1

Instrument features	Specifications
R1: External diameter	2.3 - 4.0 mm
R2: Total length	188 - 306 mm
R3: Bending angle	0° - 90°, one direction.
R4: Embedded tools	Camera, illumination system, therapeutic laser.
R5: Control type	Single-handed, intuitive operation.

The control method of the flexible tool aims to be single-handed, meaning that the surgeon can simultaneously manipulate the fetoscope, and with his/her other hand support and adjust the cannula orientation. An intuitive interface would be required such that - without additional mental load - the surgeon could remain at any time in complete control of the instrument. Table I summarizes the main specifications the developed flexible instrument has to fulfill.

III. PROPOSED DESIGN APPROACH

In order to keep the instrument approval process towards animal and human trials short, an add-on housing and actuation system on a commercially available ureteroscope the LithoVue (Boston Scientific, Natick, USA) (Fig. 3) is proposed. This single-use flexible ureteroscope is a robust medical-grade scope of 680 mm long. Its small external diameter ($\leq$ 3.23 mm), its large working channel (1.2 mm ID) as well as its integrated light source and chip-on-tip sensor makes the LithoVue a possible candidate for use in fetal surgery, and especially for TTTS treatment. Moreover, the deflection of its distal flexible tip is sufficiently large (max 270° in both directions). The tip is oriented by pushing or pulling a lever situated at the extremity of the ureteroscope handle.

However, the unaltered use of the LithoVue is no option. The flexible nature of the proximal part (part b on Fig. 3) could lead to imprecise ablations and its length is not adapted for fetal intrauterine procedures either. Finally, the current position of the lever does not provide an intuitive and ergonomic operation of the flexible tip (part a on Fig. 3).

A non-ergonomic handle can lead to surgeon's muscle fatigue, causing their performances to be less efficient [15]. It also prevents him/her from holding and orienting the cannula with his/her other hand, requiring an extra surgeon to perform the task. In order to overcome these issues, this work proposes to turn the LithoVue into an actively controlled system, whereby the control interface is directly integrated in the handle. As the LithoVue itself is a disposable instrument, a drive system integrated in an external housing is foreseen such that a new LithoVue can be easily clicked in and out of the frame. Requirements to which the add-on should satisfy are listed in Table II.

Fig. 3. LithoVue (Boston Scientific, Natick, USA) (adapted from [14]). a) distal flexible tip; b) proximal non-rigid part; c) handle.

TABLE II
SPECIFICATIONS FOR AN ACTIVE FETOSCOPE - PART II

	Additional specifications (Add-on system)
R6:	Modular setup with easy exchange of disposable LithoVue
R7:	Enabling intuitive, single-handed operation
R8:	Lightweight
R9:	Compact, allowing strong and comfortable handling
R10:	Precise control of the distal flexible part
R11:	Easy assembly and disassembly

In the literature, several works have described systems to drive otherwise manually operated flexible scopes. Ruiter *et al*. [16] and Fang *et al*. [17] proposed for example enhanced flexible scopes by fixing motors and couplings on the original instrument, or by transmitting movements using Bowden cables. However, these add-on devices are not compatible with several of the above-mentioned requirements (**R6**, **R8**, **R9**). This paper proposes a compact and lightweight add-on system respecting all the mentioned requirements (**R1**-**R11**). The surgeon can orient and insert/retract the scope as before, but can additionally access the distal bending degree of freedom which is controlled by the added drive system.

A. LithoVue modifications

The LithoVue is a cable-driven device composed of two antagonistic cables routed along the instrument shaft. At a proximal end, the cables are attached to a driving pulley/handle whereas distally, they are connected to two opposite ends of the distal tip. By pushing/pulling the lever, one cable is tensioned and the other released, allowing the distal flexible tip to bend in one or the other direction. As the surgeons want to limit the instrument to unidirectional motion (**R3**), one cable has been loosened, making the instrument bend from 0° to 135° in only one direction. Note that this does not restrict the reachable range of orientations as the surgeon can always decide to rotate the instrument about its longitudinal axis. A spring has been foreseen inside the LithoVue ensuring the return to 0° when no load is applied on the cable. In order to meet the requirements of fetal surgery, the non-rigid proximal part has been shortened and rigidified by sliding a rigid tube over that part. After these modifications, the needed maximum force and stroke to move the lever was measured. The force ensuring the return of the flexible tip to a straight configuration (i.e. to 0°) from a position of at least 90° has been estimated to be 0.7 N. The distal tip bends over 90 degrees when adjusting the lever over an angle of 1.2 rad. The spring was chosen to meet these requirements.

B. Add-on frame and actuation system

In order to satisfy the requirement in terms of size (compactness), an in-house built artificial muscle has been chosen as the actuator. This actuator is a McKibben muscle. Composed of an expandable bladder surrounded by a meshed structure, the McKibben muscle forms a thin and extremely light weight linear actuator. Once pressurized, the bladder will expand, resulting in an increase of its diameter. The individual strands of the braided mesh stay more or less constant in length. As the bladder and mesh expand in diameter, the muscle thus contracts. McKibben muscles generate relatively large output forces and displacements even for low compact diameter muscles. This actuator can also achieve good positioning accuracy. Moreover, and due to their softness and compliance, McKibben muscles are excellent candidates for instruments used in surgery [18]. A flexible air supply tube is the only connection to a distally positioned proportional valve. The weight of the muscle and the supply tube is negligible. The McKibben muscle is attached at one end to the LithoVue lever. The other end is attached to the distal part of the handle as depicted in Fig. 4. The muscle is therefore placed externally to the patient's body in order to guarantee the safety of the instrument. Any air leakage that could appear will be situated outside the body. In correspondence to **R3**, the lever moves 12 mm when the muscle contracts. It was verified that for this, the muscle needs to provide at least 4 N contraction force. A compact housing has been added (Fig. 4) in order to protect the pneumatic actuator. A pair of low-profile buttons were selected and embedded in the external housing. The location was chosen such that it would be easy for the operator to manipulate the scope with one hand and at the same time access the buttons to control the distal tip. By pushing one button or the other, the surgeon commands the pressure inside the muscle. As a result, the position of the lever is adjusted, which through the cable thus controls the bending angle of the distal tip.

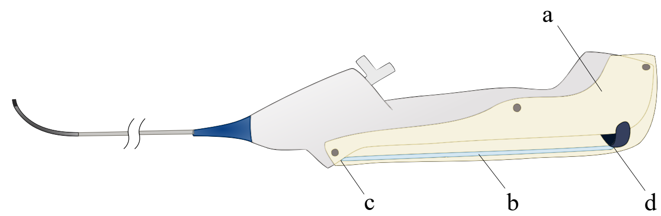


Fig. 4. Adapted LithoVue for fetal surgery. a. external housing. b. McKibben muscle. c. anchor point McKibben muscle-frame. d. anchor point McKibben muscle-LithoVue lever.

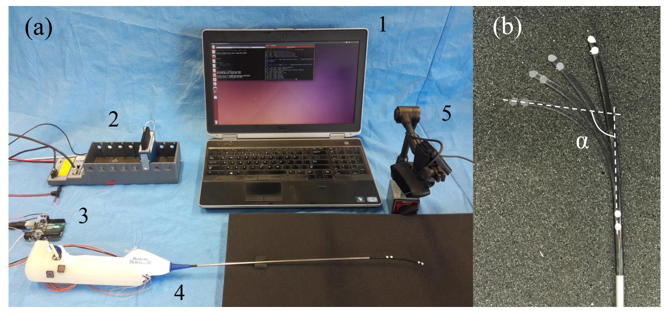


Fig. 5. a. Experimental setup used to characterize the adapted LithoVue: 1. Computer. 2. Ethercat. 3. Arduino to receive digital input from the buttons. 4. Active LithoVue fetoscope. 5. Camera. b. Calculation method of the instrument bending angle. Placement of four markers and resulting bending angle (α).

IV. IDENTIFICATION & CHARACTERIZATION

The prototype is composed of a helical twisting spring of stiffness 34.2 N.mm/rad. A McKibben muscle of 2 mm diameter (in relaxed state) and a length of 160 mm is mounted on the LithoVue. The adapted LithoVue with external housing weighs 255 g (whereas the original one weighs 304 g) and has a total length of 550 mm. The handle is 250 mm and the proximal and distal part measure together 300 mm. A measurement setup has been developed in order to characterize the device.

A. Test-bench presentation

Fig. 5a depicts the measurement setup that has been developed to characterize the active LithoVue fetoscope. A computer is used to control the air pressure, the motion of the LithoVue and process the grabbed data. To ensure the control of the electrovalve ITV0050-3MN-Q (SMC, Tokyo, Japan), OROCOS, a middleware for real time robot control was used. The proportional valve was controlled via an EtherCat module NI9144 (National Instrument, Texas, USA) and AO DAQ NI9263 (National Instrument, Texas, USA), and supplied by a Cyclon 215 air compressor (CompAir, Wisconsin, USA) that can provide a pressure of maximum 1 MPa. The output of the pneumatic valve is directly linked to the McKibben muscle inside the adapted device. The proportional valve has a response time of 0.1 s when no load is applied, and is supplied with a pressure of 0.6 MPa. For that specific supply pressure, the valve can provide a maximum flow rate of 6 l/min. The corresponding bending angle of the flexible tip is computed from tracking four white markers that were attached at different locations of the distal instrument tip (Fig. 5b). Two markers were placed on the rigid shaft, and two on the extreme tip of the flexible part to determine an axis aligned with the distal tip. The angle formed by these two axes is defined as the bending angle of the instrument (Fig. 5b). The Matlab (The Mathworks, Massachussets, US) function *imfindcircles* has been used to trace the round marker. The algorithm was tested on a mechanical micrometer device, and could predict a marker position with a 0.09 mm accuracy.

B. System identification

The characterization of the active LithoVue fetoscope has been conducted by applying 12 pressure cycles. Each cycle has a minimum pressure of 0 MPa and a maximum of 0.5 MPa, which is a safe upper limit for operating this type of muscle. The cycle period was set to 240 s. The pressure has

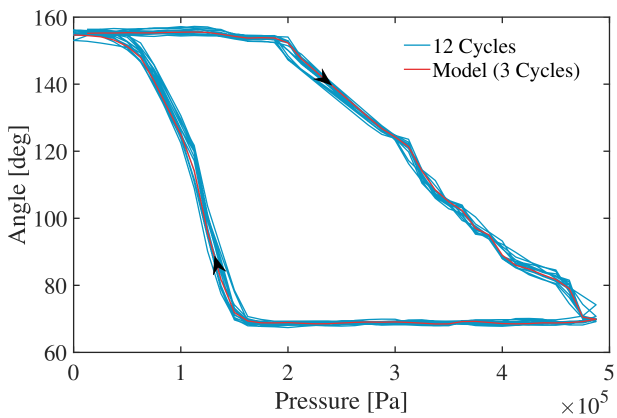


Fig. 6. Relation between the applied pressure and the bending angle of the instrument. Load curve (right curve). Unload curve (left curve).

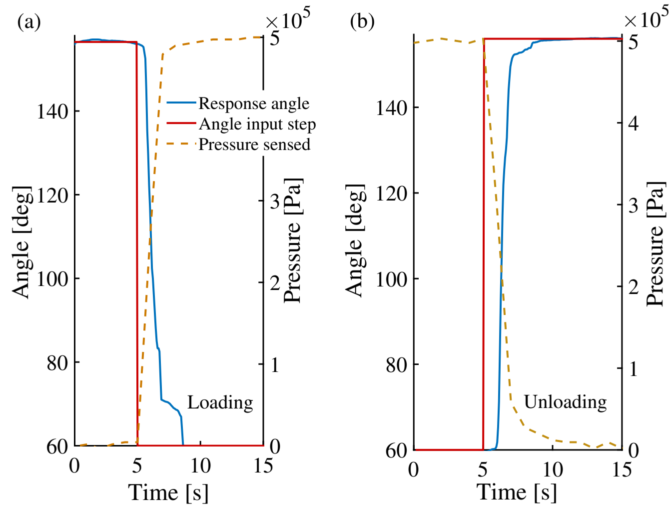


Fig. 7. Dynamic test: evaluation of the maximum time constant; a) angle response to a 0 to 0.5 MPa step; b) angle response to a 0.5 MPa to 0 Pa step.

been applied incrementally in order to allow the flexible tip to stabilize. Each increment has an amplitude of 6.25 kPa and a duration of 1.5 s. Several pressurization-depressurization cycles have been performed, and the corresponding bending angle of the instrument has been calculated using the above-mentioned method (Fig. 5b). The relation between the input pressure and the bending angle of the instrument over 12 cycles is depicted on Fig. 6. A large hysteretic effect is observed whereas the repeatability of this behavior upon full excitation is fairly good. The irregularities perceived on the load curve are due to friction induced by the cable actuation inside the LithoVue. The static friction is also expected to be the reason why the flexible tip never fully returns to a straight 180° position at rest (Fig. 6). From these data, the coordinates of plateaus extremities (constant angle over a range of pressure) can be calculated. These points, called pre-pressurization, represent the pressure from which the system will start bending. Pre-pressurizations for the loading and unloading of the instrument equals respectively at 140 kPa and 175 kPa. The characterization has been conducted with an empty-working channel. Usually, a Nd-YAG or diode laser is used to perform the coagulation. However, these fibers are stiff and not adapted for use in flexible instruments. A study showed that Holmium YAG (Ho-YAG) laser may be used for coagulation [19]. These fibers are very thin and flexible, and their insertion into the working channel has no impact on the instrument output angle.

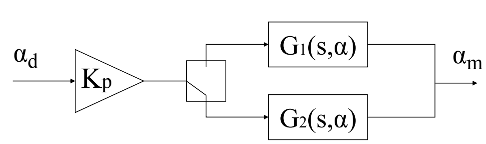
C. Static study

The precision (positioning repeatability) of the instrument was evaluated from the 12 actuation cycles and found to be 3.6°. In order to obtain the accuracy of the instrument, a model curve has been plotted and compared to the previous 12 cycles data. This model is composed of the mean angle values taken on 3 pressure loading-unloading cycles (Fig. 6). The accuracy has been evaluated to be in the order of 1.7° with this method. Finally, the drift caused by a long-period loading of the instrument has been measured. The instrument has been pressurized during 20 min., and the position difference between the initial and final position has been found to be -0.9°. This angle decrease under a long period of loading is probably due to fluctuations of the supply pressure.

D. Dynamic study

In order to evaluate the dynamic performance of the instrument, the maximum time constant in response to an input pressure step has been measured. Fig. 7 depicts the behavior of the flexible tip angle when a step of 0 to 0.5 MPa (the maximum pressure the instrument can handle) is applied. The pressure in the system has also been sensed using the PA-21Y/25BAR pressure sensor (Keller, Winterthur, Switzerland). The right part of the Fig. 7 shows the case of a step of 0.5 MPa to 0 Pa. Throughout the loading of the instrument (pressurization from 0 to 0.5 MPa), the angle response presents a delay of 0.54 s and a time constant of 0.95 s. This delay is mainly due to the switching delay of the used valve as seen on the sensed pressure curve (Fig. 7). Throughout the unloading (depressurization from 0.5 MPa to 0 Pa), the response presents a delay of 0.33 s and a time constant of 0.73 s.

By pressing a button, the surgeon is able to control the bending angle of the flexible tip. At any time, the surgeon will remain responsible for the main device motions. Only the bending of the flexible tip will be controlled via the add-on McKibben muscle. In order to keep the setup simple in the following, it is explored in how far an open-loop feed-forward control can be set to "linearize" the behavior and compensates the hysteresis. By doing so, the pre-pressurization and the non-linear relation between the input pressure and the bending angle can be made to some extent invisible to the surgeon. The open loop control of the actuator is sketched in the block diagram below:



With K_p, the scale factor of the buttons and $G(s,\alpha)$, the transfer function of the instrument. Using the data of dynamic test (Fig. 7), the device behavior can be modeled as a first order system. $G(s,\alpha)$ that takes the following forms depending on the system state; loading ($G_1(s,\alpha)$) or unloading ($G_2(s,\alpha)$):

$$G_1(s,\alpha) = \frac{F_1(\alpha)}{1+\tau_1 s} e^{-\theta_1 s} \quad , \quad G_2(s,\alpha) = \frac{F_2(\alpha)}{1+\tau_2 s} e^{-\theta_2 s} \tag{1}$$

In (1), τ_1 and τ_2 are time constants that have been previously calculated and are respectively equal to 0.54 s and 0.73 s. θ_1 and θ_2, the time delays, have also been previously calculated for a step of 0.5 MPa amplitude, and are respectively equal to 0.95 s and 0.33 s. $F_1(\alpha)$ and $F_2(\alpha)$ are related to the characteristic curve linking the input pressure and the resulting bending angle (Fig. 6). $F_1(\alpha)$ and $F_2(\alpha)$ can be modeled as a first order polynomial. The polynomial model has been obtained using the *polyfit* Matlab function. The characteristic function can therefore be expressed as the following:

$$F_1(\alpha) = \begin{cases} 160000 & (\text{if } \alpha = 156°) \\ -3680\alpha + 742590 & (\text{if } 69° < \alpha < 156°) \end{cases}$$

$$F_2(\alpha) = \begin{cases} 175000 & (\text{if } \alpha = 69°) \\ -1540\alpha + 275540 & (\text{if } 69° < \alpha < 156°) \end{cases}$$

In order to check the correct modeling of the instrument, the instrument response to a sine setpoint has been measured under open loop control. Several sinus periods have been tested: 3 s, 5 s and 7 s (Fig. 8). It can be noticed in Fig. 8 that the instrument cannot follow the full input signal for a period of 3 s. For a 5 s period, the expected curve is fairly accurately followed. However, a maximum delay of 1.06 s can be noticed between both curves. The delay upon loading is smaller than the one for unloading in accordance to the results of the step test (Fig. 7). For a period bigger than 5 s, the measured curve presents in addition an overshoot with respect to the expected curve. This can be explained by the fact that the characterization of the instrument has been realized statically. Static friction limits the amplitude of the bending angle in static experiments. Nonetheless, this friction is overcome when the instrument is tested dynamically. Table III summarizes the main features of the active LithoVue fetoscope obtained from the identification and characterization experiments. The means and standard deviations for the accuracy and precision have been taken over 12 cycles. 3 trials have been executed to determine the characteristics of the drift and the dynamic response.

However, an important problem resides in the unloading curve. Dynamically, the slope of the measured angle (Fig. 8) is too abrupt. In less than 1 s, the instrument tip relaxes about 60°. The dynamic behavior of the instrument being totally different from the static one complicates a proper open-loop control based on the static model. In order for the surgeon to be able to correctly control the device, two solutions are proposed. First, it would be possible to close the loop by integrating two sensors in the instrument. One at the very end of the flexible tip, and another one in the straight rigid part. However, little space is available inside the flexible tip to place these sensors. On the other hand, a fixation outside the instrument would increase the external diameter. Another viable solution would be to characterize the hysteresis in greater detail and use these improved models in open-loop feed-forward.

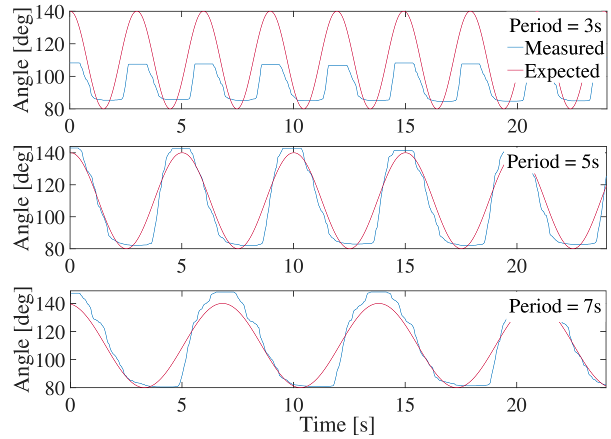


Fig. 8. Response to a sinusoidal reference trajectory for respectively 3, 5 and 7s.

TABLE III
ADAPTED LITHOVUE FEATURES

Tested features	**Characteristic**
Identification	
Pre-pressure (pressurisation)	140 kPa
Pre-pressure (depressurisation)	175 kPa
Static study	*(mean, std)*
Accuracy	0.5°, 0.5°
Precision	3.6°, 3.4°
Drift (over 1200 s)	0.75°, 0.13°
Dynamic study	*(mean, std)*
τ (loading)	0.95 s, 0.1 s
τ (unloading)	0.73 s, 0.19 s
θ (loading)	0.54 s, 0.16 s
θ (unloading)	0.33 s, 0.08 s

A human-in-the-loop experiment was designed using the active LithoVue fetoscope once with the implemented open-loop control, and once with no control at all. The user was asked to orient the flexible tip on several specific angles using the buttons in both operation modes. Beginning at rest position (156°), the flexible tip was then driven to successively reach 90°, 135°, 110° and finally 156°. Once a target is reached, the user was asked to maintain this position for a brief period of time so that it could be recorded. The K_p coefficient was set to 0.007° for both types of control, and a coefficient of 2500 $Pa/°$ was used to convert the angle in an output pressure in the case where the open-loop control was not used. Fig. 9 depicts the results of the experiment. The benefits of the open-loop control are clearly visible. The response is faster when using the implemented control. Also, higher levels of precision are reached. However, switching from 135° to 110°

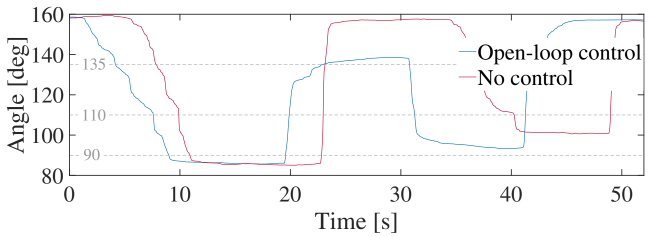


Fig. 9. Human-in-the-loop experiment, comparison of the controllability of the device with and without open-loop control. Target of successive angles: 90°, 135°, 110° from the rest position (156°).

remains an issue since the control is based on a static model. The hysteresis, when driving the tip from 135° to 110° is nevertheless smaller than the one obtained in the static study (Fig. 6).

V. USER EXPERIMENTS

The prototype has been evaluated by two experienced surgeons, a gynecologist and a pediatric surgeon, both with experience in fetal surgery. They were asked to compare two instruments : 1) an original LithoVue of which the proximal part was shortened and made stiffer by adding a rigid shaft and 2) the proposed active LithoVue fetoscope. The surgeons were asked to test both instruments in virtual reality, using a validated simulator [20]. Then, they were asked to fill in a questionnaire to evaluate the ergonomics and the ease of manipulation of these instruments.

A. Detailed Method

A mixed-reality simulator was used to simulate a realistic TTTS treatment [20]. The trainer is composed of physical and virtual components. A 4cm thick-synthetic body wall phantom renders the interaction between the instrument and the patient's thick body wall. This body wall provides the surgeon a realistic haptic feeling, generating a natural resistance upon movement of the fetoscope. The inside of the womb is rendered by the means of a VR system. The placenta and the laser coagulation of the tissue is virtually simulated. By pressing a pedal the surgeon can activate the laser. Fig. 10 provides a view on the virtual TTTS surgery. A cannula is first inserted through the body wall phantom of the simulator box to pass the instrument through. An electromagnetic (EM) motion tracking system is installed at the base of the virtual reality setup to track the instrument in real time (Aurora-NDI Medical, Cleveland, USA). A 6 DOF EM sensor is placed in the working channel of the instrument at the distal flexible tip. When the buttons are pressed, the tip of the instrument moves. The tip pose is then measured and sent to the virtual reality system, which renders images of the environment viewed from the instrument tip.

Both surgeons are asked each in turn to perform a laser ablation of the placental anastomoses, typical for TTTS. In the first part of the procedure, the surgeon has to laser selectively some preselected anastomoses seen as targets. He/she then connects these dots by a continuous ablation line (requiring continuous lasering), which represents the second part of the

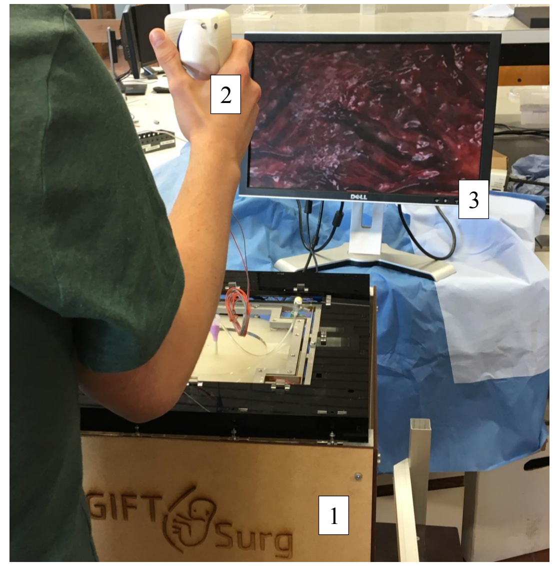


Fig. 10. User experiments with shortened rigidified LithoVue and active LithoVue fetoscope using virtual reality simulator [20]. 1) Simulator box with integrated force sensor and electromagnetic tracking system; 2) Instrument with integrated electromagnetic sensor; 3) Screen displaying the artificially generated images of the placenta.

procedure. The surgeon was asked to be as precise as possible. Both tasks are repeated three times by the surgeon. The first time, the task is conducted on a *posterior* placenta. This part is intended to get the surgeon familiar with the instrument and the simulator. Only the second and third time, respectively conducted on a *posterior* and *anterior* placenta are taken into account for the instrument evaluation. After completion of the tasks, the user is asked to fill out a questionnaire to evaluate the perceived weight, compactness and the comfort of the instrument, but also the task difficulty on a 5-point Likert scale.

B. Results

Especially for the *anterior* positioning of the placenta, which makes the TTTS procedure significantly more complex, both surgeons indicated to make less use of the cannula to orient the laser. They therefore could limit the forces on the body wall. The answers to the questionnaire are summarized in Fig. 11. A score of 5 means the instrument has been evaluated as very comfortable, very lightweight and very compact. It also means that the TTTS task (either with a *posterior* or *anterior* positioning of the placenta) has been judged as very easy with the corresponding instruments. The actuation comfort, on the other hand, refers to the comfort felt during actuation of the instrument. A score of 1 means that the instrument is absolutely not comfortable, lightweight and compact, and that the performed tasks were found very difficult. The handling comfort refers to the comfort felt when simply handling the instrument without actuating it.

While only a preliminary validation has been conducted, which prevents from making strong conclusions, one can already observe a trend that the new instrument enhances the manipulation comfort and ease of treating TTTS. The overall weight was still acceptable since the comfort scored well. This

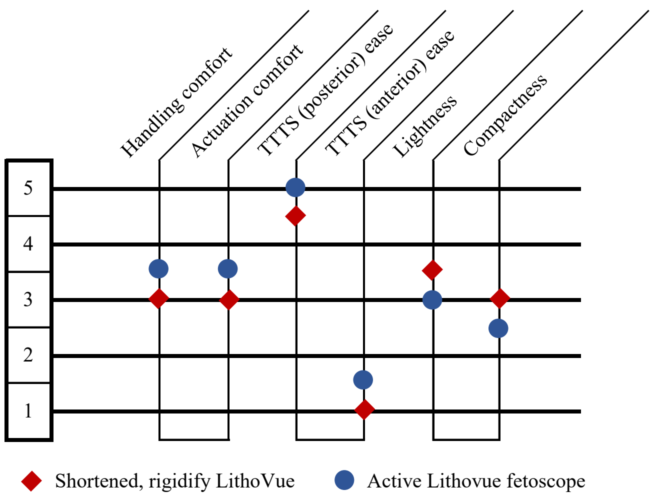


Fig. 11. Mean results of the testing of a shortened, rigidified LithoVue and active LithoVue fetoscope on a virtual TTTS task.

tendency shows that even though the instrument control is not fully optimized, the single-handed active button-controlled fetoscope is already preferred for TTTS treatment.

VI. CONCLUSIONS & FUTURE WORK

An improved flexible fetoscope tailored for TTTS treatment was presented in this paper. This device, being an adaptation of the passive flexible ureteroscope LithoVue (Boston Scientific, Natick, USA), has shown a good potential for use in TTTS surgery. Tested by two expert surgeons during virtual TTTS treatment, the device could limit variation of forces on the body wall by allowing the surgeon to reduce the use of the cannula to orient the laser. Compared to a passive, lever-actuated fetoscope, the active LithoVue fetoscope was evaluated as being more comfortable and allowing an easier accomplishment of typical TTTS treatment tasks. However, non-ideal behavior such as friction and hysteresis in the drive system negatively affected the steerability. Whereas the users managed to overcome these effects, by modeling and employing this knowledge in a feed-forward control scheme, the mental burden of the surgeons may further decrease. This could lead to improved user satisfaction. Whereas current experiments were evaluated qualitatively, a more thorough quantitative evaluation remains for further work.

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